

## Final Rule

LSA Document #13-449(F)

## DIGEST

Amends [856 IAC 4-1-1](#) to include pharmacist interns in the section and set a standard for their supervision while administering immunizations. Amends [856 IAC 4-1-2](#) to include pharmacist interns in the section and to update the section in accordance with statute. Amends [856 IAC 4-1-3](#) to include pharmacist interns in the section. Amends [856 IAC 4-1-4](#) to include pharmacist interns in the section and to update the section in accordance with statute. Amends [856 IAC 4-1-5](#) to include pharmacist interns in the section. Adds [856 IAC 4-1-7](#) to require patient consent for immunizations performed by pharmacist interns. Effective 30 days after filing with the Publisher.

[856 IAC 4-1-1](#); [856 IAC 4-1-2](#); [856 IAC 4-1-3](#); [856 IAC 4-1-4](#); [856 IAC 4-1-5](#); [856 IAC 4-1-7](#)

SECTION 1. [856 IAC 4-1-1](#) IS AMENDED TO READ AS FOLLOWS:

**[856 IAC 4-1-1](#) Education and training**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 25-26-13-10](#)

Sec. 1. (a) For purposes of this article, "pharmacist student" has the same meaning as a "pharmacist intern" registered under [IC 25-26-13-10](#).

~~(a)~~ (b) In order to qualify to administer immunizations, a pharmacist **or pharmacist intern** must successfully complete a course of training in immunization that is provided by an Accreditation Council for Pharmacy Education accredited provider and meets the standards set forth by:

- (1) the Centers for Disease Control and Prevention;
- (2) a similar health authority; or
- (3) a professional body approved by the Indiana board of pharmacy.

~~(b)~~ (c) The pharmacist **or pharmacist intern** must:

- (1) be certified in cardiopulmonary resuscitation; and
- (2) maintain certification as required by the certifying body.

~~(c)~~ (d) Training must include study materials and hands-on training and techniques for administering vaccines, comply with CDC and the Office of Safety and Health Administration guidelines, and provide instruction and experiential training in the following content areas:

- (1) Mechanisms of action for the following:
  - (A) Vaccines.
  - (B) Contraindication.
  - (C) Drug interaction.
  - (D) Monitoring after vaccine administration.
- (2) Standards for immunization practices.
- (3) Basic immunology and vaccine protection.
- (4) Vaccine-preventable diseases.
- (5) Recommended immunization schedule.
- (6) Vaccine storage management.
- (7) Biohazard waste disposal and sterile techniques.
- (8) Informed consent.
- (9) Physiology and techniques for vaccine administration.
- (10) Patient pre-vaccine and post-vaccine assessment and counseling.
- (11) Immunization record management.
- (12) Management of adverse events, including the following:
  - (A) Identification.
  - (B) Appropriate response.
  - (C) Documentation.
  - (D) Reporting.

~~(d)~~ **(e)** The qualifying pharmacist is responsible for maintaining records of training in the administration of immunizations and cardiopulmonary resuscitation of each pharmacist engaging in immunization practice within the pharmacy.

**(f) In order to administer immunizations in accordance with this article, a pharmacist intern registered under [IC 25-26-13-10](#) must be supervised within a reasonable visual and vocal distance by:**

- (1) a pharmacist;**
- (2) a physician;**
- (3) a physician assistant; or**
- (4) an advanced practice nurse.**

(Indiana Board of Pharmacy; [856 IAC 4-1-1](#); filed Dec 2, 2008, 4:03 p.m.: [20081231-IR-856070541FRA](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))

SECTION 2. [856 IAC 4-1-2](#) IS AMENDED TO READ AS FOLLOWS:

**[856 IAC 4-1-2](#) Required components of immunization protocol for administering vaccinations**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 25-26-13](#)

Sec. 2. (a) The protocol for the administration of immunizations must include the following:

- (1) For each immunization to be administered by a pharmacist, **or pharmacist intern**, the following:
  - (A) The name and strength of the vaccine.
  - (B) Precautions and contraindications.
  - (C) The intended audience or patient population.
  - (D) The appropriate dosage.
  - (E) Administration schedules in accordance with the Centers for Disease Control and Prevention guidelines.
  - (F) Appropriate routes of administration.
  - (G) Appropriate injection sites.
- (2) The length of time the pharmacist **or pharmacist intern** recommends an individual be observed for adverse effects, which shall be based on appropriate standards of care established by the physician approving the protocol. The location of the observation shall be in the general vicinity of the administering pharmacist **or pharmacist intern** to allow for ongoing evaluation.
- (3) A method to address emergency situations including, but not limited to, adverse and anaphylactic reactions.
- (4) Administration of epinephrine and appropriate dosages when required in the event of an adverse or anaphylactic reaction.
- (5) A method to notify an individual's physician and the physician approving the protocol within fourteen (14) days after administering an immunization.
- (6) A copy of the record of vaccination and notification to the primary care physician and physician approving the protocol shall be kept in accordance with the statutes and rules of the Indiana board of pharmacy.

(b) Immunization protocols must be:

- (1) approved and executed by ~~the~~ **a licensed physician actively practicing with a medical office in Indiana** prior to implementation;
- (2) maintained at the pharmacy **and available for inspection by the individual receiving the immunization**; and
- (3) renewed annually.

(c) The qualifying pharmacist is responsible for the following:

- (1) Maintaining the immunization protocols.
- (2) Ensuring that the protocols are renewed annually.
- (3) Ensuring that the name, license number, and contact information of the physician who wrote the protocol is posted where the immunization is administered.**

(Indiana Board of Pharmacy; [856 IAC 4-1-2](#); filed Dec 2, 2008, 4:03 p.m.: [20081231-IR-856070541FRA](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))

SECTION 3. [856 IAC 4-1-3](#) IS AMENDED TO READ AS FOLLOWS:

**[856 IAC 4-1-3](#) Delegation of protocol authority**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 25-26-13](#)

Sec. 3. The pharmacist **or pharmacist intern** is prohibited from delegating the administration of the immunization to another person.

(Indiana Board of Pharmacy; [856 IAC 4-1-3](#); filed Dec 2, 2008, 4:03 p.m.: [20081231-IR-856070541FRA](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))

SECTION 4. [856 IAC 4-1-4](#) IS AMENDED TO READ AS FOLLOWS:

**[856 IAC 4-1-4](#) Reporting of adverse events**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 16-38-5-2](#); [IC 25-26-13](#)

Sec. 4. (a) A pharmacist **or pharmacist intern's supervising pharmacist** shall report adverse events to the patient's primary care physician and the physician who approved the immunization protocol within seventy-two (72) hours of the pharmacist's knowledge of the adverse event.

(b) A pharmacist **or pharmacist intern's supervising pharmacist** shall report to the Vaccine Adverse Events Reporting Systems, the cooperative program for vaccine safety of the Centers for Disease Control and Prevention and the Food and Drug Administration.

(c) A pharmacist ~~may~~ **or designee shall** report the immunization of each individual to the immunization data registry maintained by the state department of health under [IC 16-38-5](#), **unless a written immunization data exception form has been completed and filed in accordance with [IC 16-38-5-2](#).**

(d) The qualifying pharmacist is responsible for ensuring that records of the reporting of adverse events is maintained by the pharmacy.

(Indiana Board of Pharmacy; [856 IAC 4-1-4](#); filed Dec 2, 2008, 4:03 p.m.: [20081231-IR-856070541FRA](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))

SECTION 5. [856 IAC 4-1-5](#) IS AMENDED TO READ AS FOLLOWS:

**[856 IAC 4-1-5](#) Immunization practice voluntary**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 25-26-13](#)

Sec. 5. (a) A pharmacist **or pharmacist intern** may not be required to:

- (1) administer an immunization; or
- (2) complete the accredited training program;

if the pharmacist **or pharmacist intern** chooses not to administer any immunization.

(b) If a pharmacist **or pharmacist intern** chooses not to administer any immunization, a pharmacist **or pharmacist intern** is not required to complete the accredited training program in order to maintain a license to practice as a pharmacist **or pharmacist intern** in this state.

(Indiana Board of Pharmacy; [856 IAC 4-1-5](#); filed Dec 2, 2008, 4:03 p.m.: [20081231-IR-856070541FRA](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))

SECTION 6. [856 IAC 4-1-7](#) IS ADDED TO READ AS FOLLOWS:

**[856 IAC 4-1-7](#) Consent required for pharmacist intern or pharmacist student to administer immunizations**

**Authority:** [IC 25-26-13-4](#); [IC 25-26-13-31.5](#)

**Affected:** [IC 25-26-13](#)

**Sec. 7. In order for a pharmacist intern or pharmacist student to administer an immunization, the pharmacist intern or pharmacist student must identify themselves to the patient as a pharmacist intern or pharmacist student and receive consent from the patient.**

*(Indiana Board of Pharmacy; [856 IAC 4-1-7](#); filed Feb 21, 2014, 4:11 p.m.: [20140319-IR-856130449FRA](#))*

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